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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,412	02/05/2004	Rudolf Tischner	P/2107-247	7277

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EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,412	TISCHNER ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/786,534.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2052004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. The claim for priority benefit of prior applications in the first paragraph on page 1 of the specification is acknowledged. The status of parent U.S. Application 09/786,534 should be updated to recite the U.S. patent number that issued from it. Further, the recitation, "based upon", in line 2 of the first paragraph of page 1 should be replaced with --the U.S. national stage filing of--.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,727,095 ('095). Although

the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '095 anticipate the subject matter of the instant claims. Instant claim 1 is directed to an isolated nucleotide sequence for reducing or preventing the expression of a protein having glutamine synthetase activity in senescing leaves of a transgenic plant, the nucleotide sequence being selected from a) the DNA sequence of SEQ ID NOs: 1 and 3, b) nucleotide sequences encoding SEQ ID NO: 2, c) nucleotide sequences complementary to the sequences of a) or b), and d) nucleotide sequences that hybridize with a nucleotide sequence of a) to c). Patented claim 1 is drawn to an isolated nucleotide sequence for reducing or preventing the expression of a protein having glutamine synthetase activity in senescing leaves of a transgenic plant, and encompasses the nucleotide sequences encompassed by instant claim 1a)-c), wherein the nucleotide sequences are from sugar beet. The sequences of SEQ ID NOs: 1-3 of '095 are the same as SEQ ID NOs: 1-3, respectively, of the instant application. Patented claim 1 limits the nucleotide sequence to being from sugar beet, whereas instant claim 1 does not recite any such limitation. The nucleotide sequences encompassed by patented claim 1 are encompassed by instant claim 1. Claims 2-15 of '095 and the instant application recite the same limitations.

Claim Objections

3. Claim 14 is objected to because of the following informalities: in line 1, the term, "gluatmine" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification indicates that cDNAs (SEQ ID NOs: 1 and 3) encoding a glutamine synthetase (SEQ ID NO: 2) have been isolated (pages 19-23, Example 1). The amino acid sequence represents the P subunit of a cytoplasmic glutamine synthetase (GS-1) from sugarbeet, and this protein represents the only subunit of the GS-I octomer, which is present in the form of a homooctamer in senescent sugarbeet leaves (paragraph bridging pages 22-23 and 1st full paragraph of page 23). This homooligomeric isoform of GS-I is only expressed in leaves during senescence (paragraph bridging pages 5-6). The specification teaches that in sugarbeet, glutamine accumulates in storage roots and causes considerable problems during sugar production (paragraph bridging pages 1-2). Glutamine synthesized during leaf aging is exported from the leaf into the storage root, or storage organ (paragraph bridging pages 1-2). The specification also teaches that vectors comprising the CaMV 35S promoter linked to different sections of this GS-I P subunit cDNA in antisense orientation were introduced into cells of sugarbeet tissue, and transgenic plants were regenerated. The antisense sequences were expressed in leaves of the transgenic plants, and glutamine synthetase activity was suppressed in senescing sugarbeet leaves (Example 3, pages 26-27).

The Federal Circuit provided the appropriate standard for written description in University of California v. Eli Lilly & Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court held that a structural description of a rat cDNA was not an adequate description of broader classes of cDNAs, because a "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subjected matter sufficient to distinguish it from other materials.

A review of the language of claim 1 indicates that it encompasses a broad genus: all isolated nucleotide sequences that reduce or prevent expression of a protein having glutamine synthetase activity in senescing leaves of a transgenic plant, the nucleotide sequence being selected from a) the DNA sequence of SEQ ID NOs: 1 and 3, b) nucleotide sequences encoding SEQ ID NO: 2, c) nucleotide sequences complementary to the sequences of a) or b), and d) nucleotide sequences that hybridize with a nucleotide sequence of a) to c). Claims 2-9 are drawn to vectors comprising said nucleotide sequence. Claims 10-13 are drawn to bacterial or plant cells, plants, or seeds comprising the vector. Claims 14 and 15 are drawn to methods that require the vector as starting material.

Claim 1 d) encompasses nucleotide sequences that hybridize under any hybridization conditions with a nucleotide sequence encompassed by parts a) to c). However, the specification does not describe isolated nucleotide sequences that encode proteins that have glutamine synthetase activity and which could hybridize to a nucleotide sequence encompassed by claim 1 a) – c) under low or moderate stringency conditions. Any two nucleotide sequences can hybridize, given the appropriate stringency conditions. The claim encompasses all hybridization

conditions, including those that would allow unrelated nucleotide sequences to hybridize, which encode proteins that do not have the activity of the sugar beet GS-1 homooctomer of SEQ ID NO: 2. The specification provides hybridization conditions in the full paragraph on page 9, which would be considered highly stringent. However, this limitation cannot be read into the claims. It is suggested claim 1 be amended to recite the hybridization conditions recited in the indicated paragraph of the specification.

Further, claim 1 d) indicates that the nucleotide sequence can hybridize to the nucleotide sequence of parts a) or b). However, as the nucleotide sequences of parts a) and c) of claim 1 encode a glutamine synthetase, nucleotides sequences that hybridize to it cannot. The specification does not describe the structure of a single nucleotide sequence that can hybridize to a coding sequence of a glutamine synthetase, wherein the hybridizing sequence itself also encodes a glutamine synthetase. It is suggested that part d) of claim 1 be amended to indicate that the nucleotide sequence hybridizes with the nucleotide sequence of c). Given the breadth of the claims and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of nucleotide sequences encompassed by the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6, 9, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Temple et al. (Mol. Gen. Genet., 1993, Vol. 236, pages 315-325).

The claims are broadly drawn towards any isolated nucleotide sequences that reduce or prevent expression of a protein having glutamine synthetase activity in senescing leaves of a transgenic plant, the nucleotide sequence being selected from a) the DNA sequence of SEQ ID NOs: 1 and 3, b) nucleotide sequences encoding SEQ ID NO: 2, c) nucleotide sequences complementary to the sequences of a) or b), and d) nucleotide sequences that hybridize with a nucleotide sequence of a) to c); vectors comprising said nucleotide sequence; bacterial or plant cells, plants, or seeds comprising the vector.

Temple et al. teach transgenic plants transformed with a plasmid comprising a nucleotide sequence encoding a glutamine synthetase, either in sense or antisense orientation. The nucleotide sequence is operably linked to a promoter at its 5' end and a transcription terminator at its 3' end. Expression of the sequence in antisense orientation reduced expression of glutamine synthetase in leaves of the transgenic plants (page 318). The properties of reducing expression of glutamine synthetase in senescing leaves of transgenic plants when expressed in antisense orientation and of hybridizing to the nucleotide sequence of instant claim 1 c), are inherent to the sequence taught in the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7, 8, 11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Temple et al. (Mol. Gen. Genet., 1993, Vol. 236, pages 315-325) in combination with Lindsey et al. (J. Exp. Bot., 1990, Vol. 41, pages 529-536), Stockhaus et al. (Proc. Natl. Acad. Sci., 1987, Vol. 84, pages 7943-7947), and Smart et al. (Plant Cell, 1991, Vol. 3, pages 647-656).

The claims are broadly drawn towards a vector comprising the nucleotide sequence of claim 1, wherein the nucleotide sequence is operably linked to an inducible regulatory sequence, or confers tissue specificity and/or time specificity; or a transgenic sugarbeet cell comprising a vector comprising the nucleotide sequence of claim 1; or a seed of a plant wherein the seed comprises a plant cell comprising a vector comprising the nucleotide sequence of claim 1; or a method for altering glutamine metabolism in sugarbeet.

Temple et al. is discussed above.

Temple et al. do not teach sugarbeet plants, inducible regulatory sequences, tissue specific and/or time specific regulatory sequences.

Lindsey et al. teach a method for producing transgenic sugarbeet plants, and assert that sugarbeet is a commercially important crop and is a major sucrose producer (pages 531-534).

Stockhaus et al. teach the leaf-specific ST-LS1 promoter (pages 7943-7945).

Smart et al. teach a heat-inducible promoter, HS68721 (page 648).

It would have been obvious and within the scope of one of ordinary skill in the art use the method of expressing the antisense sequence of the glutamine synthase gene and reducing glutamine synthase levels in senescing leaves of Temple et al. with other plants, such as sugarbeets, following an appropriate plant transformation method, such as that taught by Lindsey

et al. One of ordinary skill would have been motivated to express the sequence in sugarbeet plants, given that sugarbeet its commercial importance, as asserted by Lindsey et al. It also would have been obvious to express the antisense sequence using a leaf-specific promoter, such as the ST-LS1 promoter taught by Stockhaus et al., or an inducible promoter, such as the heat-inducible promoter disclosed in Smart et al. One would have been motivated to use an inducible or tissue-specific promoter, for the obvious reason of controlling the timing or area of expression. It also would have been obvious to produce seed from the transgenic plants, for the obvious purpose of propagation.

7. Claims 1-15 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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July 21, 2006

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